

### Section I (Amendments to the Claims)

Please cancel claims 49-53, 56-58, and 61-62, amend claim 54, and add new claims 63-65, as set out in the following listing claims 1-65 of the application.

1. – 53. (Cancelled)

54. (Currently Amended) A dermatological composition consisting of water[[:]] and the following ingredients in the following percentages by weight, based on total weight of the composition: urea in an amount of 1-50% by weight; disodium EDTA in an amount of 0.05-0.3% by weight; sodium polyacrylate in an amount of 0.1-1.5% by weight; stearic acid in an amount of 3.0-8.0% by weight; glyceryl stearate in an amount of 2.0-10.0% by weight; soybean sterol in an amount of 1.0-4.0% by weight; shea butter in an amount of 0.5-10% by weight; sunflower oil in an amount of 2.0-15% by weight; butylated hydroxytoluene in an amount of 0.05-0.5% by weight; and triethanolamine in an amount of 0.25-2.5% by weight, wherein weight percentages of all ingredients total to 100 weight percent.

55. (Previously Presented) The dermatological composition of claim 54, wherein the amount of urea in the composition is from 20% to 50% by weight, based on the total weight of the composition.

56. – 58. (Cancelled).

59. (Previously Presented) The dermatological composition of claim 54, wherein the amount of urea in the composition is from about 20 to about 41 %.

60. (Previously Presented) The dermatological composition of claim 54, wherein the amount of urea in the composition is about 40%.

61. – 62. (Cancelled).

63. (New) The dermatological composition of claim 54, in the form of a lotion.

64. (New) The dermatological composition of claim 54, in the form of a cream.

65. (New) A dermatological formulation, comprising:

a base composition; and

a therapeutic agent selected from the group consisting of: wound healing agents, anti-inflammatory agents, glucocorticosteroids, hydrocortisone, triamcinolone, betametamethasone, ibuprofen, ketoprofen, methyl salicylate, anti-infective agents, bacitracin, polymixin B, mupirocin, neomycin, enzymes, anti-fungal agents, anti-viral agents, acne-combating agents, rosacea-combating agents, dermatitis-combating agents, and topical immunomodulator agents,

wherein the base composition consists of water and the following ingredients in the following percentages by weight, based on total weight of the composition: urea in an amount of 1-50% by weight; disodium EDTA in an amount of 0.05-0.3% by weight; sodium polyacrylate in an amount of 0.1-1.5% by weight; stearic acid in an amount of 3.0-8.0% by weight; glyceryl stearate in an amount of 2.0-10.0% by weight; soybean sterol in an amount of 1.0-4.0% by weight; shea butter in an amount of 0.5-10% by weight; sunflower oil in an amount of 2.0-15% by weight; butylated hydroxytoluene in an amount of 0.05-0.5% by weight; and triethanolamine in an amount of 0.25-2.5% by weight, wherein weight percentages of all ingredients total to 100 weight percent.

## **Section II (Remarks)**

### **Amendment of the Claims**

To advance the application to allowance, claims 49-53, 56-58, and 61-62 have been cancelled, claim 54 has been amended, and new claims 63-65 have been added.

Claim 54 has been amended consistent with the Examiner's remark at page 21 of the November 17, 2008 Office Action that "amending claim 54 to include specific amounts (or ranges) of each ingredient may be allowable."

Accordingly, claim 54 has been amended to set forth the ranges for the specific ingredient amounts as described in Table 1 of the application at pages 6-8 thereof. The recital of water in such claim is consistent with the statement in paragraph [0031] that "Compositions of Table 1 may be formed with water" and the recital that weight percentages of all ingredients total to 100 weight percent is found in paragraph [0028] of the application.

New claim 63 depends from claim 54 and recites that the composition is in the form of a lotion, consistent with Example 1 and the description in paragraph [0054] ("dermatological lotion composition in accordance with the invention"). New claim 64 also depends from claim 54 and recites the composition in the form of a cream, consistent with the disclosure in Example 2 and paragraph [0068] ("dermatological cream composition in accordance with the invention").

New claim 65 is of independent form, and recites a therapeutic formulation comprising a base composition and a therapeutic agent selected from the group consisting of therapeutic agents specified in paragraph [0054] of the specification, and a base composition, recited as in claim 54. Such claim is consistent with and supported by the disclosure in paragraph [0040] ("[I]n therapeutic formulations, the compositions of the invention may be utilized as base compositions for topical administration of therapeutic agents such as wound healing agents, anti-inflammatory agents, . . .").

Accordingly, all now-pending claims 54-55, 59-60 and 63-65 are fully consistent with and supported by the original disclosure of the application. No new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the foregoing amendments.

#### **Rejection of Claims Under 35 USC §112, First Paragraph**

In the November 17, 2008 Office Action, claims 49-53, 58 and 61 were rejected under 35 USC §112, first paragraph for failing to comply with the written description requirement, based on various recitals of relative proportions and amounts of specific ingredients in relation to one another.

In order to advance the application to allowance, applicant has cancelled claims 49-53, 58 and 61, the claims in which the Examiner had specifically asserted new matter to be present.

With such cancellation of claims 59-53, 58 and 61, the §112, first paragraph rejection is now moot. It is correspondingly requested that the §112, first paragraph rejection now be withdrawn.

#### **Rejection of Claims on Reference Grounds, and Traversal Thereof**

In the November 17, 2008 Office Action, then pending claims 49-62 were rejected on various reference grounds, including:

- a rejection of claims 45-52 under 35 USC §103(a) as unpatentable over Durr, et al. in view of Gallina in view of Glassman in view of Guthauser in view of Huard;
- a rejection of claims 45-53 under 35 USC §103(a) as unpatentable over Durr in view over Durr, et al. in view of Gallina in view of Glassman in view of Guthauser in view of Huard in view Znalden, et al. in view of Wikipedia; and
- a rejection of claims 49-62 under 35 USC §103(a) as unpatentable under Durr, et al. in view of Gallina in view of Glassman in view of Guthauser in view of Huard, in view of Znalden, et al. in view of Wikipedia in view of

Garrison, et al. in view of Hill, et al. in view of McNulty, et al. in view of Barker.

The foregoing rejections are traversed, in application to the claims 54-55, 59-60 and 63-65 as now amended/added and pending in the application. Consideration of such amended/added claims 54-55, 59-60 and 63-65 is requested, in light of the ensuing remarks.

#### **Patentable Distinction of the Now-Pending Claims Over the Cited References**

Claims 54-55, 59-60 and 63-65 are directed to a dermatological composition (claims 54-55, 59-60 and 63-64) and formulation containing the dermatological composition in combination with a therapeutic agent (claim 64). Such dermatological composition of claim 54, having specified concentration ranges for its ingredients, has a “superior character, relative to compositions having ingredients outside of such concentration ranges” (page 8, paragraph [0032] of the application).

Such dermatological compositions “may be utilized for treatment of a wide variety of dermal conditions and adverse physiological states manifesting dermally...are usefully employed as skin moisturizers, skin softening agents, skin debridement agents...as well as base compositions for therapeutic, e.g., pharmacological, formulations,” as described at page 10, paragraph [0039] of the application.

The composition of the claimed invention thus is dermatologically beneficial in its own right, as well as being a superior base for therapeutic agents that are combined with it.

The now-pending claims 54-55, 59-60 and 63-65 include independent claim 54, from which each of claims 55, 59-60 and 63-64 directly depends, and independent claim 65, which requires the dermatological composition of claim 54.

Thus, all of the now pending claims require

“[A] dermatological composition consisting of water and the following ingredients in the following percentages by weight, based on total weight of the composition: urea in an amount of